IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TENNESSEE NORTHERN DIVISION

XODUS MEDICAL, INC.,)
ALESSIO PIGAZZI, and GLENN KEILAR,)
Plaintiffs,)
v.) No. 3:18-cv-413-JPM
PRIME MEDICAL, LLC., and SYMMETRY SURGICAL INC.))
Defendants.)
XODUS MEDICAL, INC., ALESSIO PIGAZZI, and GLENN KEILAR,)
Plaintiffs,)
V.) No. 3:18-cv-414-JPM
PRIME MEDICAL, LLC., and SYMMETRY SURGICAL INC.)))
Defendants.)
XODUS MEDICAL, INC., ALESSIO PIGAZZI, and GLENN KEILAR,)
Plaintiffs,)
V.	No. 3:18-cv-415-JPM
G&T INDUSTRIES, INC.)
Defendant.)

ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT UNDER THE ON-SALE BAR OF SECTION 102 AND DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT UNDER 35 U.S.C. § 101

Before the Court is Defendants Prime Medical LLC, Symmetry Surgical Inc. and G&T Industries, Inc.'s Motion for Summary Judgment Under the On-Sale Bar of Section 102, filed under seal on October 19, 2021. (ECF No. 260.)¹ Plaintiffs filed a Response in Opposition on November 12, 2021. (ECF No. 286.) Defendants filed a Reply on November 22, 2021. (ECF No. 311.) For the reasons discussed below, Defendants' Motion for Summary Judgment Under the On-Sale Bar of Section 102 is **DENIED**.

Also before the Court is Defendants' Motion for Summary Judgment Under 35 U.S.C. § 101, filed under seal on October 19, 2021. (ECF No. 258.) Plaintiffs filed a Response in Opposition on November 19, 2021. (ECF No. 303.) Defendants filed a Reply on December 7, 2021. (ECF No. 331.) For the reasons discussed below, Defendants' Motion for Summary Judgment Under 35 U.S.C. § 101 is **DENIED**, and Summary Judgment is **GRANTED** for Plaintiffs as to the patents-in-suit's eligibility under 35 U.S.C. § 101.

I. BACKGROUND

The background of these three cases is provided in this Court's Claim Construction Order. (ECF No. 138.) This background is quoted below:

This consolidated patent action concerns devices for positioning a patient at an angle during surgery. Three patents are at issue. (ECF No. 79 at PageID 878.) Defendants in each case filed counterclaims seeking declaratory judgment of noninfringement, invalidity, and unenforceability of the subject patents. (ECF Nos. 13, 14; Case No. 3:18-cv-414, ECF Nos. 14, 16; Case No. 3:18-cv-415, ECF No. 35.)

The Technology

Some surgical procedures require a patient to be tilted during surgery. (ECF No. 95 at PageID 1334.) The Trendelenburg position is the common clinical name for when the patient is tilted so that the patient's feet are elevated. When the patient is tilted in the opposite manner, so that the patient's head is elevated over the patient's feet, the position is called the "Reverse Trendelenburg position." When

¹ Unless otherwise noted, all docket numbers refer to Case No. 3:18-cv-413.

the patient is tilted on the table, if insufficiently cushioned or otherwise secured, the patient may slide down the table during surgery. This can cause injury. (<u>Id.</u>)

The asserted patents are:

- (1) U.S. Patent 8,511,314 (the "'314 patent") entitled "Method of securing a patient onto an operating table when the patient is in the Trendelenburg position and apparatus therefor including a kit," which was filed on February 21, 2013, and issued on August 20, 2013.
- (2) U.S. Patent 8,464,720 (the "'720 Patent"), entitled "Method of securing a patient onto an operating table when the patient is in the Trendelenburg position and apparatus therefor including a kit," which was filed on January 9, 2013, and issued on June 18, 2013.
- (3) U.S. Patent 9,161,876 (the "876 Patent"), entitled "Method of securing a patient onto an operating table when the patient is in the Trendelenburg position and apparatus therefor including a kit," which was filed on August 2, 2013, and issued on October 20, 2015.

All three patents contain both method and device claims. All three patents claim priority to the same U.S. Patent App. Serial No. 13/346,852, filed January 10, 2012. (ECF No. 1-3 at PageID 33.) The '314 Patent (ECF No. 1-2) is a continuation of the '720 Patent, and the '876 Patent is a continuation of both the '314 Patent and the '720 Patent. (Case No. 3:18-cv-414, ECF No. 1-2 at PageID 11.) The specifications of the '314, '720, and '876 Patents are identical, but the claim language is not. (See, e.g., ECF No. 94 at PageID 1144.)

Xodus is a company that makes items for use in surgery, including patient positioning systems. (ECF No. 95 at PageID 1334.) Plaintiffs allege that they used their patented inventions to create and market the PINK PAD®, which is a kit that includes a set of foam materials and restraints for preventing a patient from sliding during surgery when the patient is in the Trendelenburg or Reverse-Trendelenburg position. (ECF No. 95 at PageID 1334; Declaration of Dr. Maheswari Senthil ("Senthil Decl."), ECF No. 105-1 at PageID 1972.) Xodus asserts that the PINK PAD® met a long-felt need and had commercial success. (ECF No. 95 at PageID 1335.)

Prime and Symmetry market and sell the following models of Trendelenburg table pads: "STP100, STP100S, STP100S-WING, STP200/S, STP150 S, and STP100 PED Trendelenburg O.R. Table Pads." (ECF No. 95 at PageID 1335.) Plaintiffs accuse these products of infringing their patents. The Defendants' pads are blue, and for the purposes of discussion, the Court refers to the allegedly infringing pads as "the Blue Pads." These pads were produced to the Court during the Claim Construction Hearing and are maintained as Exhibit 4. (ECF No. 123.) Prime is a medical device brand and seller that advertises pads for positioning patients in the Trendelenburg position on its website. G&T

manufactures the allegedly infringing pads for Prime, and then sells the blue pads to Prime. (Case No. 3:18-cv-415, ECF No. 38 at PageID 314.) G&T explains that it has an "exclusive manufacturer/distributor relationship" with Prime, and that "G&T manufactures the products accused of infringement in both actions and supplies the accused products exclusively to Prime Medical." (Id.) It does not appear that Xodus and Prime had any commercial relationship prior to this litigation, and currently they are competing in the market for surgical foam pads.

(ECF No. 138 at PageID 2880–83.)

II. LEGAL STANDARD

A party is entitled to summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A fact is 'material' for purposes of summary judgment if proof of that fact would establish or refute an essential element of the cause of action or defense." <u>Bruederle v. Louisville Metro Gov't</u>, 687 F.3d 771, 776 (6th Cir. 2012).

"In considering a motion for summary judgment, [the] court construes all reasonable inferences in favor of the nonmoving party." Robertson v. Lucas, 753 F.3d 606, 614 (6th Cir. 2014) (citing Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986)). "The moving party bears the initial burden of demonstrating the absence of any genuine issue of material fact." Mosholder v. Barnhardt, 679 F.3d 443, 448 (6th Cir. 2012) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)).

"Once the moving party satisfies its initial burden, the burden shifts to the nonmoving party to set forth specific facts showing a triable issue of material fact." Mosholder, 679 F.3d at 448–49; see also Fed. R. Civ. P. 56(e); Matsushita, 475 U.S. at 587. "When the non-moving party fails to make a sufficient showing of an essential element of his case on which he bears the burden of proof, the moving parties are entitled to judgment as a matter of law and summary judgment is proper." Martinez v. Cracker Barrel Old Country Store, Inc., 703 F.3d 911, 914 (6th Cir. 2013)

(quoting <u>Chapman v. UAW Local 1005</u>, 670 F.3d 677, 680 (6th Cir. 2012) (en banc)); <u>see also Kalich v. AT & T Mobility, LLC</u>, 679 F.3d 464, 469 (6th Cir. 2012).

To "show that a fact is, or is not, genuinely disputed," both parties must do so by "citing to particular parts of materials in the record," "showing that the materials cited do not establish the absence or presence of a genuine dispute," or showing "that an adverse party cannot produce admissible evidence to support the fact." Bruederle, 687 F.3d at 776 (quoting Fed. R. Civ. P. 56(c)(1)); see also Mosholder, 679 F.3d at 448 ("To support its motion, the moving party may show 'that there is an absence of evidence to support the nonmoving party's case." (quoting Celotex Corp., 477 U.S. at 325)). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge[.]" Martinez, 703 F.3d at 914 (alteration in original) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986)).

"The court need consider only the cited materials, but it may consider other materials in the record." Fed. R. Civ. P. 56(c)(3). "[T]he district court has no 'duty to search the entire record to establish that it is bereft of a genuine issue of material fact." Pharos Capital Partners, L.P. v. Deloitte & Touche, 535 F. App'x 522, 523 (6th Cir. 2013) (per curiam) (quoting Tucker v. Tennessee, 539 F.3d 526, 531 (6th Cir. 2008), abrogation recognized by Anderson v. City of Blue Ash, 798 F.3d 338 (6th Cir. 2015)). "[J]udges are not like pigs, hunting for truffles' that might be buried in the record." Emerson v. Novartis Pharm. Corp., 446 F. App'x 733, 736 (6th Cir. 2011) (alteration in original) (quoting United States v. Dunkel, 927 F.2d 955, 956 (7th Cir. 1991)).

The decisive "question is whether 'the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." <u>Johnson v. Memphis Light Gas & Water Div.</u>, 777 F.3d 838, 843 (6th Cir. 2015) (quoting

Anderson, 477 U.S. at 251-52). Summary judgment "shall be entered' against the nonmoving party unless affidavits or other evidence 'set forth specific facts showing that there is a genuine issue for trial." Rachells v. Cingular Wireless Emp. Servs., LLC, No. 1:08CV02815, 2012 WL 3648835, at *2 (N.D. Ohio Aug. 23, 2012) (quoting Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 888 (1990)). "[A] mere 'scintilla' of evidence in support of the non-moving party's position is insufficient to defeat summary judgment; rather, the non-moving party must present evidence upon which a reasonable jury could find in her favor." Tingle v. Arbors at Hilliard, 692 F.3d 523, 529 (6th Cir. 2012) (quoting Anderson, 477 U.S. at 251). "[I]n order to withstand a motion for summary judgment, the party opposing the motion must present 'affirmative evidence' to support his/her position." Mitchell v. Toledo Hosp., 964 F.2d 577, 584 (6th Cir. 1992) (citing Anderson, 106 S. Ct. at 2514; Street v. J.C. Bradford & Co., 886 F.2d 1472, 1479 (6th Cir. 1989)). "[C]onclusory assertions, unsupported by specific facts made in affidavits opposing a motion for summary judgment, are not sufficient to defeat a motion for summary judgment." Rachells, 2012 WL 3648835, at *2 (quoting Thomas v. Christ Hosp. & Med. Ctr., 328 F.3d 890, 894 (7th Cir. 2003)). Statements contained in an affidavit that are "nothing more than rumors, conclusory allegations and subjective beliefs" are insufficient. Mitchell, 964 F.2d at 584–85.

III. ANALYSIS

A. On-Sale Bar Under Section 102

Defendants seek summary judgment that the apparatus claims of the patents-in-suit are invalid under the on-sale bar of pre-AIA 35 U.S.C. § 102(b). (ECF No. 260 at PageID 6787.) "[T]he on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale," and "[s]econd, the invention must be ready for patenting." <u>Pfaff v. Wells Elecs., Inc.</u>, 525 U.S. 55, 67 (1998). "[T]he first determination

of the § 102(b) analysis must be whether the subject of the barring activity met each of the limitations of the claim, and thus was an embodiment of the claimed invention." <u>Scaltech Inc. v.</u> <u>Retec/Tetra, LLC</u>, 178 F.3d 1378, 1383 (Fed. Cir. 1999).

Defendants contend that "Plaintiffs took widely known, commercially available foam and cut it to a size useful for their intended use," and additionally, that "[v]iscoelastic foams were routinely sold and used as mattress toppers." (ECF No. 260 at PageID 6796.) As a result, Defendants assert that "[v]iscoelastic foam pads embodying the invention as claimed in the Asserted Apparatus Claims were the subject of commercial offers for sale in the United States more than one year prior to the critical priority date [(June 1, 2012)] of the patents-in-suit." (Id. at PageID 6797.) Defendants also contend that the Asserted Apparatus Claims were "ready for patenting" more than one year prior to the priority date because "the invention was depicted in drawings or described in writings of [a] sufficient nature to enable a person of ordinary skill in the art to practice the invention." (Id. at PageID 6798.)

In response, Plaintiffs contend that "there is no evidence that these foams were ever used by a third-party to hold a patient in an inclined position, such as Trendelenburg," and that "Dr. Reynolds' claim charts in his report do not map the Third-Party Foams to each and every element of the Asserted Claims, which is itself sufficient to deny summary judgment." (ECF No. 286 at PageID 8245.) Plaintiffs further contend that "Dr. Reynolds' unsupported conclusions are the only 'evidence' supposedly supporting Defendants' position," and that while "Dr. Reynolds states that he tested present-day Third-Party Foams in 2021 and they were successful in holding a patient in the Trendelenburg position, [he] has provided no evidence of his testing in his report." (Id. at PageID 8246.) Plaintiffs also assert that there "is no evidence that the foams tested today, in 2021, are identical in composition and function to the pre-2011 versions of those foams." (Id.) Plaintiffs

also contest that the invention was "ready for patenting" more than one year prior to the priority date. (Id. at PageID 8249–51.)

In their Reply, Defendants provide a chart² showing, they allege, that "the Prior Art Foam meets every element of the Asserted Apparatus Claims." (ECF No. 311 at PageID 9225–26.) Defendants also contend that "[i]nstead of demonstrating a genuine issue of material fact, Plaintiffs attempt to deflect by attacking Dr. Reynold[s]'s expert opinions page after page." (Id. at PageID 9229.) Defendants assert that "Dr. Reynolds' expert report, opinions, deposition testimony, testing, and analyses do not form the basis of Defendants' Motion. Indeed, Defendants' Motion does not reference, rely upon, or cite to Dr. Reynolds' opinions a single time." (Id.)

As an initial matter, Defendants' claim-by-claim analysis does not adequately show that each claim limitation is met such that summary judgment is warranted. For example, Defendants assert that the claim term "a pad configured to be placed on a tiltable medical procedure table" is met because "the Prior Art Foams are pads." (<u>Id.</u> at PageID 9225.) It does not logically follow that any foam pad of any size could meet the limitation of being "configured to be placed on a tiltable medical procedure table" because, as just one reason alone, a foam pad could be too large or unwieldy to use on an operating table.

Further, Plaintiffs' contentions regarding Dr. Reynolds's expert report are relevant to this Motion and whether the prior art foams would invalidate the Asserted Apparatus Claims under the on-sale bar. While Defendants' claim analysis in their Reply may not reference his analysis, the Defendants' Motion does use his report.³ (See, e.g., ECF No. 260 at PageID 6796.) ("These

² Providing a claim-by-claim analysis on reply is untimely, but because there are further factual disputes which merit denying this Motion for Summary Judgment, the Court did not deny Defendants' Motion solely for the untimely disclosures. The claim chart also references "the '320 Patent," which is not one of the patents-in-suit. (See ECF No. 311 at PageID 9225.) The Court used Claim 1 in the '314 Patent as a reference.

³ Defendants' Motion also references Dr. Pickens's expert report, which was later stricken. (See ECF No. 275.)

mattress toppers were shown by Drs. Pickens and Reynolds to inherently possess the characteristics needed to hold a patient in the Trendelenburg position.") As a result, Plaintiffs' issues with Dr. Reynolds's expert report went to whether there is a genuine dispute of material fact that would preclude summary judgment.

Having determined that Defendants have not met their burden of establishing that an embodiment of the invention was commercially available more than one year before the priority date, the Court need not address Defendants' contention that the invention was "ready for patenting," the other requirement for the on-sale bar to apply. Defendants' Motion for Summary Judgment Under the On-Sale Bar of Section 102 is **DENIED**.

B. Section 101

Defendants also seek summary judgment under 35 U.S.C. § 101. (ECF No. 258 at PageID 6409.) Defendants contend that the Asserted Claims are directed to abstract ideas that are ineligible under 35 U.S.C. § 101. (Id.) Thirty-five U.S.C. § 101 sets forth that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." "Eligibility under 35 U.S.C. § 101 is a question of law, based on underlying facts." SAP America, Inc. v. InvestPic, LLC, 898 F.3d 1161, 1166 (Fed. Cir. 2018) (internal citations omitted).

It is well-settled that "[1]aws of nature, natural phenomena, and abstract ideas are not patentable." Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 134 S. Ct. 2347, 2354 (2014) (quoting Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013)). An invention, however, "is not rendered ineligible for patent simply because it involves an abstract concept." Id.

There is an exception under § 101 for patents that apply an abstract concept "to a new and useful end." <u>Id.</u> (quoting <u>Gottschalk v. Benson</u>, 409 U.S. 63, 67 (1972)).

The unanimous Supreme Court decision in Alice provided a two-part analysis for determining whether the application of an abstract idea would be patent-eligible: (1) "whether the claims at issue are directed to one of those patent-ineligible concepts;" and (2) "whether the additional elements [of a claim] 'transform the nature of the claim' into a patent-eligible application." Id. at 2355 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012)). The first stage of the Alice inquiry looks "at the 'focus' of the claims" and their "character as a whole." Elec. Power Grp., LLC v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016) (citing Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1335–36 (Fed. Cir. 2016)). When reached, the second stage inquiry looks "more precisely at what the claim elements add—specifically, whether, in the Supreme Court's terms, they identify an 'inventive concept' in the application of the ineligible matter to which (by assumption at stage two) the claim is directed." Id. at 1353 (internal citations omitted).

For the reasons discussed below, the Court finds that the patent claims here are not directed to an abstract idea and, thus, Defendants' Motion fails at Alice step one. See Alice, 134 S. Ct. at 2355 ("We set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts."). In recent years, the Federal Circuit has further clarified what constitutes an abstract idea by focusing on the presence of a "technological improvement." See In re TLI Comme'ns LLC Patent Litig., 823 F.3d 607, 612 (Fed. Cir. 2016) ("We recently clarified that a relevant inquiry at step one is 'to ask whether the claims are directed to an improvement to computer

functionality versus being directed to an abstract idea."") (citing Enfish, 822 F.3d at 1335 (contrasting claims "directed to an improvement in the functioning of a computer" with claims "simply adding conventional computer components to well-known business practices")).

Defendants contend that the Asserted Claims are abstract because they recite the following: "placing a patient support pad on an operating table, positioning a patient on the patient support pad, tilting the operating pad at an angle, and having the frictional characteristics inherent in the patient support pad prevent the patient from sliding." (ECF No. 258 at PageID 6419.) "Taking representative Claim 1 of the '720 Patent for the Method Claims, the focus of the claim is on the physical characteristics of the claimed viscoelastic pad and its use in holding a patient in place when placed upon said pad when used in the Trendelenburg position." (Id. at PageID 6422.)

In response, Plaintiffs contend that the claims are not directed to an abstract idea at all:

The claims recite a manner of positioning a patient in the Trendelenburg position using a specific method, such as securing the patient and Trendelenburg pad in a certain manner, and specific physical, real-world components, such as specially configured viscoelastic pads, so that patients do not risk pressure injuries that occur when being positioned using conventional positioning methods and arrangements. . . . The Asserted Claims, evidenced by the claims and specification of the Patents-in-Suit, can be found to "focus on a specific means or method" that improves the relevant technology and are "directed to a result or effect," namely minimizing patient movement and injury using a material that had not been used for that purpose before – this is not abstract.

(ECF No. 303 at PageID 9114.) (quoting <u>Card-Monroe Corp. v. Tuftco Corp.</u>, 270 F. Supp. 3d 967, 1008 (E.D. Tenn. 2017).) Plaintiffs also contend that Defendants "overgeneralize the Asserted Claims" by implying that the patents-in-suit are "directed to the idea of friction." (<u>Id.</u> at PageID 9119.)

In reply, Defendants contend that "the Asserted Claims here simply seek to invoke the natural laws of friction and the natural laws inherent in foam material, and nothing more, to achieve

the result of preventing a patient from moving when in the Trendelenburg position." (ECF No. 331 at PageID 9508.) (citing Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1298 (Fed. Cir. 2020).)

American Axle is distinguishable from the Asserted Claims. In American Axle, the Federal Circuit held that a patent was "directed to the use of a natural law: Hooke's law" because the claim at issue "simply instructs the reader to tune the liner to achieve a claimed result, without limitation to particular ways to do so." 967 F.3d at 1298. Defendants over-generalize the claims here by asserting that they are directed to the use of friction and gravity, physical laws of nature, to prevent patient movement. (See ECF No. 258 at PageID 6419–23.) The Federal Circuit, however, requires that "courts 'must be careful to avoid oversimplifying the claims' by looking at them generally and failing to account for the specific requirements of the claims." McRO, Inc. v. Bandai Namco Games Am., Inc., 837 F.3d 1299, 1313 (Fed. Cir. 2016) (quoting In re TLI Commc'ns LLC Patent <u>Litig.</u>, 823 F.3d at 611). Here, the claims require more than simply applying natural laws such as friction and gravity to prevent patient movement and thus are not directed to an abstract idea. See, e.g., '720 Patent Claim 1 (requiring limitations such as "a single-use, viscoelastic Trendelenburg pad comprising a rectangular shape and viscoelastic polyurethane" where the pad must have "sufficient thinness to stabilize said patient" and "sufficient thickness and sufficient compliance to permit formation of a cavity"). Because the Asserted Claims are not directed to a patentineligible concept, Defendants' Motion for Summary Judgment Under 35 U.S.C. § 101 is **DENIED**, and summary judgment that the Asserted Claims are not invalid under 35 U.S.C. § 101 is **GRANTED** for Plaintiffs.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motions for Summary Judgment Under the On-Sale Bar of Section 102 and for Summary Judgment Under 35 U.S.C. § 101 are **DENIED**.

IT IS SO ORDERED, this 22nd day of December, 2021.

/s/ Jon P. McCalla JON P. McCALLA UNITED STATES DISTRICT JUDGE